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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/913,967

12/31/2001

Wilhelmus Evergadu Hennink

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02/28/2008

MORRISON & FOERSTER LLP

12531 HIGH BLUFF DRIVE

SUITE 100

SAN DIEGO, CA 92130-2040

EXAMINER

FUBARA, BLESSING M

ART UNIT

PAPER NUMBER

1618

MAIL DATE

DELIVERY MODE

02/28/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/913,967

Applicant(s)

HENNINK ET AL.

Examiner

BLESSING M. FUBARA

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1618

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 December 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 2, 6, 7, 12, 13, 15-17, 24 and 27-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 6, 7, 12, 13, 15-17, 24 and 27-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-946)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Examiner acknowledges receipt of request for extension of time, amendment and remarks filed 12/06/07. Claims 3-5, 8-11, 14, 21-23, 25 and 26 are canceled. New claims 27-31 are added. Claims 1, 2, 6, 7, 12, 13, 15-17 and 24 are amended. Claims 1, 2, 6, 7, 12, 13, 15-17, 24 and 27-31 are pending.

Response to Arguments

Previous rejections that are not reiterated herein are withdrawn.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1, 2, 6, 7, 12, 13, 15-17, 24 and 27-31 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is written description. (New in view of the amendment)

35 USC 112 requires that the “specification shall contain written description of the invention.” Amended claims 1 and 15 recite “chiral region” and the specification does not provide support for polymers/oligomers/co-oligomers having chiral regions. Applicant does not appear to have possession of the claimed invention.

4. Claims 1, 2, 6, 7, 12, 13, 15-17, 24 and 27-31 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for dextran polymer onto which is grafted lactide, does not reasonably provide enablement for all hydrophilic polymers and all oligomers and co-oligomers, oligomers that comprise first and second chiral region. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims, for reasons set forth in the Office action of 08/07/2007 and reiterated below. This is scope of enablement.

Claim 1 is directed to hydrogel composition that contains a mixture of water soluble or water dispersible polymers A and B, each is grafted with oligomers or co-oligomers, the oligomers or co-oligomers having first chiral region for polymer A and second chiral region for polymer B, the chirality of the second region is opposite the chirality of the first region.

Claim 15 polymerizes a first chiral monomer in the presence of suitable initiator, polymerizes second chiral monomer, the chirality of the second chiral monomer is opposite the chirality of the first chiral monomer; mixing the product of steps c and d in an aqueous system such that the oligomers or co-oligomers interact non-covalently.

The water soluble polymer or water dispersible polymer of claim 1 and 15 encompass all water soluble polymers or all water dispersible hydrophilic polymers. Claim 2, which appears

to limit the oligomers and co-oligomers is included in the rejection because applicant in the remarks at page 14 says that “applicants respectfully note that claim 2 is a dependent claim and does not define the oligomers of claim 1.”

The following Wands factors are considered below:

The Nature of the Invention: The invention is directed to all water-soluble or water dispersible polymers that are substituted with any and all oligomers or co-oligomers.

The Breadth of the claims: The scope of the claims is open to any water-soluble or water dispersible polymers and any and all oligomers or co-oligomers. The scope of the claims is not commensurate with the enabling disclosure where L- and D-lactide oligomers are grafted onto dextran, a water-soluble polymer.

The state of the prior art: The prior art is what the prior art knows. Ethyl cellulose is known in the art as a water insoluble polymer, while hydroxyethyl cellulose, methylcellulose and polyvinylpyrrolidone are water-soluble polymers and several more. In similar manner, there are other oligomers such as bifunctional styrene oligomer, which is not one of those listed in the specification and recited in dependent claim 2.

The quantity of Experimentation Needed: Guidance is provided only for dextran and lactide, and this guidance is not commensurate with the full scope of all polymers and oligomers claimed. While the specification further lists a number of polymers and oligomers on pages 11 and 12 at lines 21-36 and 1-10 respectively, the list is by no means commensurate with the scope of all oligomers and polymers claimed. Applicant on page 7 of the remarks filed 11/17/06, at the last two lines of the first full paragraph, states that it is known in the art that all optically active polyesters do not form stereocomplexes. There is thus an element of unpredictability in at least oligomers and their ability to form stereocomplexes. Thus, the listing of the oligomers represents

an invitation to fishing expedition to determine which of the oligomers can form stereocomplexes and be grafted on to any polymer.

Therefore, the quantity of experimentation needed to practice the full scope of the claimed invention is undue and the full scope of the claimed invention has not been enabled by the specification.

Applicant may overcome this rejection by reciting in at least claims 1, 5, and 15 the enabled dextran polymer and oligomer derived from lactide

Response to Arguments

5. Applicant's arguments filed 12/06/07 with respect to the scope of enablement have been fully considered but they are not persuasive.

Applicant states that a) polymers that are not water soluble or water dispersible hydrophilic polymers or polymers grafted with oligomers that lack the required complementary chiral regions are clearly not envisioned; b) the test for enablement is not merely quantitative, that if experimentation is merely routine or if the specification provides reasonable guidance with respect to the direction in which the experimentation should proceed, then the guidance provided is adequate because the first paragraph does not require complete absence of experimentation; c) in the instant case applicant has provided detailed guidance for determining the rheology behavior of hydrogel samples under standard experimental conditions and using standard equipment; d) the specification teaches the skilled artisan how to make and use the hydrogel of the claimed invention and the claims as amended is reasonably enabled.

6. **Response:**

7. The rejection is scope of enablement and as it regards a) or b) the test for scope of enablement is whether the scope of enablement provided the skilled artisan by the disclosure is commensurate with the scope of protection sought by the claims. In this case, the answer is no that the scope of enablement provided to one skilled in the art by the disclosure is not commensurate with the scope of protection sought by the claims. Since the disclosure provides enablement for lactide grafted onto dextran, the skilled artisan would have to experiment with a large number of sets of chiral monomers and hydrophilic polymers in order to make and use the full scope of the claimed invention, and such experimentation is undue. Regarding c) and d), the skilled artisan cannot make what the skilled artisan does not know because the claims have not defined what the product is. Thus, because what is unknown cannot be made, one cannot also determine the rheology of what can not be made.

The disclosure enables L- and D-lactide oligomers that are grafted onto dextran. Thus, the scope of enablement provided to one skilled in the art by the disclosure is not commensurate with the scope of protection sought by the claims. One skilled in the art is therefore not enabled to make and use the full scope of the claimed invention without undue experimentation. The experimentation is undue because, the artisan would have to experiment with a host of chiral monomers from chiral amino acids to chiral acids to chiral compounds for grafting onto any water soluble polymers. One cannot make what one does not know and specifically the claims have not defined the product with sufficient clarity for the artisan to make and use the claimed invention commensurate with the scope of the claims.

Therefore, the quantity of experimentation needed to practice the full scope of the claimed invention is undue and the full scope of the claimed invention has not been enabled by

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the specification. Applicant may overcome this rejection by reciting in at least claims 1 and 15 the enabled dextran polymer and oligomer derived from lactide.

8. Claims 6 and 7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 6: The meets and bounds of “cellulose derivatives,” “related copolymers” of poly(lysine) and poly(glutamic acid) are not defined in the claims.

Response to Arguments

9. Applicant's arguments filed 12/06/07 have been fully considered but they are not persuasive.

10. Applicant requests the withdrawal of the rejection of claim 6 as being indefinite because applicant argues that cellulose and poly(amino acid) co-polymers are well known in the field of chemistry. The rejection is maintained because the boundaries of cellulose derivatives is not defined.

Double Patenting

11. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting

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ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

12. Claims 1, 2, 6, 7, 12, 13, 15-17, 24 and 27-31 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 6-24 of copending Application No. 10/581,369 (US 20070185008). Although the conflicting claims are not identical, they are not patentably distinct from each other because while copending claim 1 recites stereocomplex hydrogel, the hydrogel composition of the examined claims is also a stereocomplex by virtue of the presence of monomers/oligomers/ooligomers having opposite chirality.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Objections

Claim 2 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Applicant in the remarks at page 14 stated "applicants respectfully note that claim 2 is a dependent claim and does not define the oligomers of claim 1." Since claim 2 does not define the oligomers or co-oligomers of claim 1, then claim 2 does not further limit claim 1.

Correction is respectfully requested.

No claim is allowed.

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BLESSING M. FUBARA whose telephone number is (571)272-0594. The examiner can normally be reached on 7 a.m. to 5:30 p.m. (Monday to Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Blessing M. Fubara/
Examiner, Art Unit 1618

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

Application Number

Application/Control No.

09/913,967

Applicant(s)/Patent under
Reexamination

HENNINK ET AL.

Examiner

BLESSING M. FUBARA

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